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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,048	05/24/2001	Leon W.M.M. Terstappen	890-2FWC/CIP/CPA/CON	2293

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 01/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,048	TERSTAPPEN ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-52* is/are pending in the application.

4a) Of the above claim(s) *17,18 and 30-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction requirement was improper. This is not found persuasive because the examination of the instant invention is based on its own merit. Furthermore, the prior art search for a method of obtaining phage particles already constitutes a search involving multiple databases, of which are constantly expanding. The additional search for cells harboring phage particles and antibodies are not necessarily overlapping nor is it co-extensive. As such, the additional search for cells and antibody, phage antibodies or antibody fragments would constitute a burdensome search for the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Accordingly, claims 9-52 of the instant application are pending, claims 17-18, 30-52 are withdrawn from further consideration as being drawn to a non-elected invention. Therefore, claims 9-16 and 19-29 are examined on the record.

3. This application contains claims 17-18 and 30-52 are drawn to an invention non-elected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

4. The disclosure is objected to because of the following informalities: the priority data must be updated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the recitation of the phrase "one or more times", it is not clear as to how many "more times" are required to accomplish the method. As such the metes and bounds of the term cannot be determined.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 9-14, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by de Kruif (PNAS USA 1995 April;92:3938-3942). Claims are drawn to a method of obtaining phage particles comprising an antibody fragment (Fab or scFv) directed against an antigen associated with the surface of a target cell to isolate target cells from non-target cells, wherein the cells are separated by flow cytometry, wherein the cells are detectably labeled with fluorescence, and the process is repeated. The reference of de Kruif *et al* teach a method of obtaining phage particles through the incubation of phage particles, that express scFv antibody fragments on its surface, with a mixed leukocytes cell population. The cells expressing an antigen recognized by the phage particles were sorted by fluorescence activated cell sorting.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 19-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Kruif *et al* in view of Winter *et al* (Annu. Rev. Immunol. 1994;12:433-455). Claims are drawn to a method of obtaining phage particles comprising an antibody fragment directed against an antigen associated with the surface of a target cell, wherein the method comprises a library of phage particles that express antibody fragments on the surface, incubation with non-target antigens, incubation with target cells, separation of target cells, and recovery of the phage particles bound to said target cells, wherein the non-target antigen is immobilized on a surface. The reference taught by de Kruif *et al* teach of the isolation of phage particles by incubating with a

heterogenous population of cells (see above), however, de Kruif *et al* do not teach a method of obtaining phage particles by utilizing a non target cell immobilized on a solid surface. Winter *et al* however do teach of a method of isolating phage particles by utilizing a solid support medium.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate phage particle by pre-screening phage particles with a non-specific antigen prior to the addition of a specific antigen located on the surface of a cell because it was already taught that cells in a heterogeneous cell population could be separated by using phage display technology, and that the pre-screening process of pre-incubation with non-specific antigens was already known, as taught by Winter *et al*. One of skill in the art would have been motivated to combine the references because de Kruif *et al* teach the method of isolation of phage particles by using heterogeneous populations of cells and further points to the Winter *et al* reference for guidance on methods of using immobilization techniques for phage recovery. One could have expected a reasonable amount of success in the method because it was both techniques were proven effective and functional and that the combination of the two separate techniques would have been obvious.

Double Patenting

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 9-11, 13, 15, and 16 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, and 6 of prior U.S. Patent No. 6265150. This is a double patenting rejection.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
December 27, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600